



United States  
Department of  
Agriculture

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Marketing and  
Regulatory  
Programs

## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-08

Animal and Plant  
Health Inspection  
Service

**Subject:** Diagnostic Test Kits for Scrapie and Chronic Wasting Disease

Veterinary Services

**To:** Biologics Licensees, Permittees, and Applicants  
Veterinary Services Management Team  
Directors, Center for Veterinary Biologics  
Area Veterinarians in Charge, VS  
State Veterinarians

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Biologics  
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### I. PURPOSE

The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is accepting veterinary biologics product license and permit applications for diagnostic test kits (including “rapid tests”) intended as an aid in the diagnosis of scrapie or chronic wasting disease.

### II. BACKGROUND

Numerous test methods (e.g., immunohistochemistry, ELISA, Western blot) and commercial test kits have been developed to aid in the diagnosis of transmissible spongiform encephalopathy (TSE) diseases. Some of these kits have been approved by foreign regulatory officials (e.g., European Union, Japan) for use in their TSE testing programs. Scrapie and chronic wasting disease are TSE diseases that are endemic in the United States. Therefore, the CVB will accept and consider license and permit applications for diagnostic test kits intended to aid in the diagnosis of either of these specific diseases.

If approved by the CVB, diagnostic test kits for scrapie or chronic wasting disease will be issued a U.S. Veterinary Biological Product License (domestically manufactured products) with the following restrictions:

1. Distribution and use in the United States shall be under the supervision or control of USDA, APHIS, Veterinary Services.
2. Export distribution shall be limited to authorized recipients designated by proper animal health regulatory officials—under such additional conditions as these authorities may require.



Veterinary Services – Safeguarding Animal Health  
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1-800-877-8339

U.S. Veterinary Biological Permits for Distribution and Sale (foreign manufactured products) shall be issued with the following restrictions:

1. Distribution and use in the United States shall be under the supervision or control of USDA, APHIS, Veterinary Services.
2. All ingredients of animal origin used to produce this product were not obtained from ruminants that have been in any country cited in 9 CFR 94.18 or countries considered to be of equivalent status by the National Center for Import/Export.
3. During the manufacturing process, the manufacturing facility does not receive, store, or process any ingredients of ruminant origin from countries cited in 9 CFR 94.18.
4. The product complies with all other provisions of 9 CFR 113.53.

### **III. ACTION**

Interested parties should refer to Title 9, Code of Federal Regulations, Subchapter E; Veterinary Services (VS) Memorandum 800.50, Basic License Requirements for Applicants; VS Memorandum 800.101, U.S. Veterinary Biological Product Permits for Distribution and Sale; and VS Memorandum 800.73, General Requirements for Immunodiagnostic Test Kits, for guidance in applying for licensure. This information is available on the CVB website:

**[www.aphis.usda.gov/vs/cvb/regsandguidance.htm](http://www.aphis.usda.gov/vs/cvb/regsandguidance.htm)**

Applications and supporting materials should be submitted to the CVB-Licensing and Policy Development for review.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics